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POCKET NO.: SMAR-0013

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Michael R. Hayden, et al.

Serial No.: 10/019,341

Filing Date: May 3, 2002

LPL VARIANT THERAPEUTICS

Group Art Unit: Not Yet Assigned

Examiner: Not Yet Assigned

DATE OF DEPOSIT: September 26, 2002

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TYPED NAME: Phillip A. Singer REGISTRATION NO.: 40,176

Assistant Commissioner for Patents Washington, D.C. 20231

Dear Sir:

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

In accordance with §1.97(b), since this Information Disclosure Statement is being

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Date: September 26, 2002

Phillip A. Singer

Registration No. 40,176

WOODCOCK WASHBURN LLP One Liberty Place - 46th Floor Philadelphia, PA 19103 Telephone: (215) 568-3100

Facsimile: (215) 568-3439

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Sheet 1 of 15

PRADEM Orm PTO-1449 Modified	Docket No. SMAR-0013	Serial No. 10/019,341		
List of Patent and Publications Cited by Applicant (Use several sheets if necessary)	Applicant Hayden, M.R. et	t al.		
U.S. Department of Commerce Patent and Trademark Office	Filing Date May 3, 2002	Group Not Yet Assigned		
OTHER DOCUMENTS (Including Aut	hor, Title, Date, Pert	tinent Pages, Etc.)		
Ascadi, G. et al., "Human dystrope injection of DNA constructs", Nat	<u>-</u>			
2 Altschul, S.F. et al., "Basic Local 403-410				
3 Anderson, W. F., "The Best of Tire 629				
Retrovirus-Mediated Gene Transfe	Armentano, D. et al., "Expression of Human Factor IX in Rabbit Hepatocytes by Retrovirus-Mediated Gene Transfer: Potential for Gene Therapy of Hemophilia B", <i>Proc. Natl. Acad. Sci. USA</i> , 1990 , 87, 6141-6145			
Triglycerides to Incidence of Athe	Assmann, G. MD. et al., "Relation of High-Density Lipoprotein Cholesterol and Triglycerides to Incidence of Atherosclerotic Coronary Artery Disease(the PROCAM Experience)", Am. J. Cardiol., 1992, 70, 733-737			
6 Baldari, et al., "A novel leader per interleukin 1β in Saccharomyces of		_		
Baliga, et al., "High fat meal induction coronary artery disease", 70th Scient				
8 U. Beisiegel, "Lipoprotein Metabo A23	U. Beisiegel, "Lipoprotein Metabolism", European Heart Journal, 1998, 19, A20-A23			
chylomicronemia caused by mutat	Benlian, P. MD., Ph.D. et al., "Premature atherosclerosis in patients with familial chylomicronemia caused by mutations in the lipoprotein lipase gene", <i>The New England Journal of Medicine</i> , 1996 , 335, 848-854			
	Berkner, K.L. "Development of Adenovirus Vectors for the Expression of Heterologous Genes", <i>BioTechniques</i> , 1988 , 6(7), 616-629			
EXAMINER	EXAMINER DATE CONSIDERED			

OCT 0 2 2002

TECH CENTER 1600/2900 Sheet 2 of 15 Form PTO-1449 Modified Docket No. Serial No. **SMAR-0013** 10/019,341 List of Patent and Publications Applicant Cited by Applicant Hayden, M.R. et al. (Use several sheets if necessary) U.S. Department of Commerce Filing Date Group Patent and Trademark Office May 3, 2002 Not Yet Assigned OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) Bethesda: Lipids Research Clinics Program, NIH(National Institute of Health) Publication, 1974, Vol 75 Black, M.E. et al., "Creation of Drug-Specific Herpes Simplex Virus Type 1 12 Thymidine Kinase Mutants for Gene Therapy", Proc. Natl. Acad. Sci. USA, 1996, 93, 3525-3529 Brunzell, J.D. et al., "Structure-function relationships of lipoprotein lipase: mutation 13 analysis and mutagenesis of the loop region", Journal of Lipid Research, 1993, 34, (9), 1593-1602 Brunzell, J.D. "Familial Lipoprotein Lipase Deficiency and Other Causes of the 14 Chylomicronemia Syndrome", The Metabolic and Molecular Bases of Inherited Disease, New York, NY, McGraw-Hill, Inc., 1995, 59, 1913-1932 Cavazzana-Calvo, M. "Gene Therapy of Human Severe Combined Immunodeficiency 15 (SCID)-X1 Disease", Science, 2000, 288, 669-672 16 Chowdhury, J.R, et al., "Long-Term Improvement of Hypercholesterolemia After ex Vivo Gene Therapy in LDLR-Deficient Rabbits", Science, 1991, 254, 1802-1805 17 Clapp, D.W. et al., "Fetal Liver Hematopoietic Stem Cells As a Target for In Utero Retroviral Gene Transfer", Blood, 1991, 78, 1132-1139 18 Cohen, J.C. et al., "Postprandial lipemia and chylomicron clearance in athletes and in sedentary men", Am. J. Clin. Nutr., 1998, 49, 443-447 19 Cristiano, R.J. et al., "Hepatic Gene Therapy: Adenovirus Enhancement of Receptor-Mediated Gene Delivery and Expression in Primary Hepatocytes", Proc. Of the Nat'l Academy of Sciences, 1993, 90, 2122-2126 Curiel, D.T. et al., "Adenovirus Enhancement of Transferrin-Polylysine-Mediated 20 Gene Delivery", Proc. Natl. Acad. Sci. USA, 1991, 88, 8850-8854 **DATE CONSIDERED EXAMINER**

^{*} A copy of these references will not be forwarded to the U.S. Patent and Trademark Office since they are believed to be too voluminous and easily obtainable by the Examiner.

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Sheet 3 of 15

Form Form	PTO-1449 Modified	Docket No. SMAR-0013	Serial No. 10/019,341	
	f Patent and Publications Cited by Applicant everal sheets if necessary)	Applicant Hayden, M.R. et al.		
	Department of Commerce at and Trademark Office	Filing Date May 3, 2002	Group Not Yet Assigned	
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)				
21	Dai, Y. et al., "Gene Therapy Via Pri Factor IX Protein Following Transpla 1992, 89(22), 10892-10895		-	
22	Danos, O. et al., "Safe and Efficient Generation of Recombinant Retroviruses with Amphotropic and Ecotropic Host Ranges", <i>Proc. Natl. Acad. Sci. USA</i> , 1988 , 85(17), 6460-6464			
23	Davies, Michael J. MD. "Stability and Instability: Two Faces of Coronary Atherosclerosis: The Paul Dudley White Lecture 1995", <i>Circulation</i> , 1996 , 94(8), 2013-2020			
24	Eglitis, M.A. et al., "Gene Expression in Mice after High Efficiency Retroviral-Mediated Gene Transfer", <i>Science</i> , 1985 , 230, 1395-1398			
25	Eyre-Walker, A. et al., "High genomic deleterious mutation rates in hominids", <i>Nature</i> , 1999 , 397, 344-347			
26	Excoffon, K. J.D. et al., "Correction of Hypertriglyceridemia and Impaired Fat Tolerance in Lipoprotein Lipase-Deficient Mice by Adenovirus-Mediated Expression of Human Lipoprotein Lipase", Arterioscler. Thromb. Vasc. Biol., 1997, 17(11), 2532-2539			
27	Faure, L. et al, "Prevalence of common lipoprotein lipase (LPL) gene mutation Ser447Stop is increased while prevalence of Asn291Ser mutation is decreased in centenarians", <i>Atherosclerosis</i> , 1997, 134, p 1.P.26			
. 28	Feinleib, M. et al., "The Framingham Offspring Study. Design and Preliminary Data", <i>Prevent. Med.</i> , 1975 , 4, 518-525			
. 29	Ferry, N. et al., "Retroviral-Mediated Gene Transfer Into Hepatocytes in vivo", 1991, 88(19), 8377-8381			
30	Fisher, R.M. et al., "Common variation in the lipoprotein lipase gene: effects on plasma lipids and risk of atherosclerosis", <i>Atherosclerosis</i> , 1997 , 135, 145-159			
EXAMINER		DATE CONSIDER	ED	

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TRADEMAN!	Form	PTO-1449 Modified	Docket No. SMAR-0013	Serial No. 10/019,341	
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	U.S. Department of Commerce Filing Date Group Patent and Trademark Office May 3, 2002 Not Yet Assigned				
	ОТНЕ	CR DOCUMENTS (Including Autho	r, Title, Date, Pertine	nt Pages, Etc.)	
	31	Flotte, T.R. et al., "Gene Expression Epithelial Cells", Am. J. Respir. Cell			
	32	Flotte, T.R. et al., "Expression of the Cystic Fibrosis Transmembrane Conductance Regulator from a Novel Adeno-associated Virus Promoter", J. Biol. Chem., 1993, 268(5), 3781-3790			
	33		Gagne, E. et al., "Analysis of DNA Changes in the LPL Gene in Patients With Familial Combined Hyperlipidemia", <i>Arterioscl. Thromb.</i> , 1994 , 14(8), 1250-1257		
	34	Gagne, SE. et al., "A common truncation variant of lipoprotein lipase (Ser447X) confers protection against coronary heart disease: the Framingham Offspring Study' Clin. Genet., 1999, 55(6), 450-454			
	35	with Postheparin Plasma Lipase Acti	C. et al., "Linkage and Association Studies of the Lipoprotein Lipase Gene theparin Plasma Lipase Activities, Body Fat, and Plasma Lipid and ein Concentrations: The HERITAGE Family Study", <i>Metabolism</i> , 2000 , 32-439		
	36	Gaziano, J. MD et al., "Fasting Trigl Myocardial Infarction", Circulation,	-		
	37	Gehrisch, S. MD., "Common Mutatic Clinical Significance", Curr. Atheros			
*	38	Goeddel, Gene Expression Technolog Academic Press, San Diego, Californ		ology, 1990, vol 185,	
	39	Groenemeijer, B.E. MD. Et al., "Genetic Variant Showing a Positive Interaction with beta-Blocking Agents with a Beneficial Influence on Lipoprotein Lipase Activity, HDL Cholesterol, and Triglyceride Levels in Coronary Artery Disease Patients: The Ser sup 447-Stop Substitution in the Lipoprotein Lipase Gene", Circulation, 1997, 95(12), 2628-2635			
	Gronholdt, M-L M. MD. Et al., "Echo-Lucency of Computerized Ultrasound Imag of Carotid Atherosclerotic Plaques are Associated with increased Levels of Triglyceride-Rich Lipoproteins as Well as Increased Plaque Lipid Content", Circulation, 1998, 97(1), 34-40				
EXAMII	NER		DATE CONSIDER	ED	

^{*} A copy of these references will not be forwarded to the U.S. Patent and Trademark Office since they are believed to be too voluminous and easily obtainable by the Examiner.

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Sheet 5 of 15

		10/019,341		
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U.S. Department of Commerce Patent and Trademark Office	Filing Date May 3, 2002	Group Not Yet Assigned		
OTHER DOCUMENTS (Including Auth	or, Title, Date, Pertine	nt Pages, Etc.)		
Hamsten, A. MD. Et al., "Increased Plasminogen Activator in Young Su Med., 1985, 313(25), 1557-1563	-			
	Hasdai, D. MD. Et al., "Coronary Endothelial Dysfunction in Humans is Associated with Myocardial Perfusion Defects", Circulation, 1997, 96(10), 3390-3395			
	Hayden, MR. Et al., "Gene environment interaction and plasma triglyceride levels: th crucial role of lipoprotein lipase", <i>Clin Genet</i> , 1994 , 46, 15-18			
Lipoprotein Lipase Gene Causes Li	Henderson, H.E. et al., "Amino Acid Substitution (lle 194THR) in Exon 5 of the Lipoprotein Lipase Gene Causes Lipoprotein Lipase Deficiency in Three Unrelated Probands", Journal of Clinical Investigation, 1991, 87, 2005-2011			
patients with coronary artery disease	Henderson, H.E. et al., "Lipoprotein lipase activity is decreased in a large cohort of patients with coronary artery disease and is associated with changes in lipids and lipoproteins", <i>Journal of Lipid Research</i> , 1999 , 40, 735-743			
46 Henikoff, S. et al., "Amino Acid Su Natl. Acad. Sci. USA, 1992, 89(12),		n Protein Blocks", <i>Proc</i> .		
Hermonat, P.L. et al., "Use of Aden Cloning Vector: Transduction of Ne Culture Cells", Proc. Natl. Acad. Sc	eomycin resistance into	Mammalian Tissue		
	Herz, J. et al., "Adenovirus-Mediated transfer of Low Density Lipoprotein Receptor Gene Acutely Accelerates Cholesterol Clearance in Normal Mice", <i>Proc. Natl. Acad. Sci. USA</i> , 1993, 90(7), 2812-2816			
49 Hexter, A. "Selective Advantage of	the Sickle-Cell Trait",	Science, 1968 , 160, 436		
	Hodis, H.N. et al., "Triglyceride-rich lipoproteins and the progression of coronary artery disease", Curr. Opin. Lipid, 1995, 6, 209-214			
EXAMINER	DATE CONSIDER	ED		

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Sheet 6 of 15

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& TRADEMARK	Form	PTO-1449 Modified	Docket No. SMAR-0013	Serial No. 10/019,341	
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		Department of Commerce at and Trademark Office	Filing Date May 3, 2002	Group Not Yet Assigned	
	OTHE	R DOCUMENTS (Including Autho	r, Title, Date, Pertine	nt Pages, Etc.)	
	51	Hokanson, J.E. "Lipoprotein lipase g quantitative analysis of population-ba		-	
	52	Hokanson, J.E. et al., "Plasma triglyodisease independent of high-density population-based prospective studies	lipoprotein cholesterol	level: a meta-analysis of	
*	53	Hosmer, et al., Applied Logistic Regr	ession, New York: Joh	n Wiley & Sons, 1989, 1	
	54	Huber, B.E. et al., "Retroviral-Mediated Gene Therapy for the Treatment of Hepatocellular carcinoma: An Innovative Approach for Cancer Therapy", <i>Proc. Natl. Acad. Sci. USA</i> , 1991 , 88, 8039-8043			
	55	Hwu, P. et al., "Functional and Molecular Characterization of Tumor-Infiltrating Lymphocytes Transduced with Tumor Necrosis Factor-α cDNA for the Gene Therapy of Cancer in Humans", J. Immunol., 1993, 150, 4104-4115			
	56	Inoue, T. et al., "Serum Level of Ren Endothelium-Dependent Coronary V Sessions of the AHA, 2208			
	57	Jukema, J. et al., "Coronary Artery Disease/Myocardial Infarction: Effects of Lipid Lowering by Pravastin on Progression and egression of Coronary Artery Disease in Symptomatic Men with Normal to Moderately Elevated Serum Cholesterol Levels: The Regression Growth Evaluation Statin Study (REGRESS)", Circulation, 1995, 91(10), 2528-2540			
	58	Jukema, J. et al., "Prevention of Cardiovascular Disease: The Asp sub 9 Asn Mutation in the Lipoprotein Lipase Gene is Associated with Increased Progression of Coronary Atherosclerosis", Circulation, 1996, 94(8), 1913-1918			
	59	Kastelein, J.J.P. MD, PhD, et al., "Lipoprotein Lipase Activity is Associated with Severity of Angina Pectoris", Circulation, 2000, 102(14), 1629-1633			
	60	Kaufman, R.J. et al., "Translational efficiency of polycistronic mRNAs and their utilization to express heterologues genes in mammalian cells", <i>EMBO J.</i> , 1987 , 6, 187-193			
EXAMINI	ER		DATE CONSIDER	ED	

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Sheet 7 of 15

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	Department of Commerce at and Trademark Office	Filing Date May 3, 2002	Group Not Yet Assigned	
ОТНЕ	R DOCUMENTS (Including Author	r, Title, Date, Pertine	nt Pages, Etc.)	
61	Kay, M.A. et al., "Hepatic Gene Then Antitrypsin in Mice after Direct Gene 1992, 3,641-647			
62	Keyt, B.A. et al., "A Faster-Acting and More Potent Form of Tissue Plasminogen Activator", <i>Proc. Natl. Acad. Sci. USA</i> , 1994 , 91(9), 3670-3674			
63	Khoury, et al., Fundamentals of Genetic Epidemiology: Oxford University Press, Oxford, 1993, 49-54			
64	Kleinbaum, et al., "Multiple Regression Analysis: General Considerations", Applied Regression Analysis and Other Multivariable Methods, 2 nd ed. Boston, MA: PWS-Kent Publishing Company, 1988, 102-340			
65	Kramer, W. et al., "Liver-specific Drug Targeting by Coupling to Bile Acids", J. Biol. Chem., 1992, 267(26),18598-18604			
66	Krapp, A. et al., "Structural features in lipoprotein lipase necessary for the mediation of lipoprotein uptake into cells", J. Lipid. Res., 1995, 36(11), 2362-2373			
67	7 Kugiyama, K. et al. "Remnant Lipoproteins Impair Endothelium-dependent Vasomotor Functions in Human Coronary Arteries", 70th Scientific Sessions of the AHA, 2207			
68	Kuivenhoven J.A. et al., "Ser 447stop Mutation in Lipoprotein Lipase Is Associated With Elevated Hdl Cholesterol Levels in Normolipidemic Males", <i>Arteriosclerosis, Thrombosis and Vascular Biology</i> , 1997 , 17, 595-599			
69	Kurjan, J. et al, "Structure of a Yeast Pheromone Gene (Mfα): A Putative α-Factor Precursor Contains Four Tandem Copies of Mature α-Factor", Cell, 1982, 30, 933-943			
70	Lemarchand, P. et al., "Adenovirus-Mediated Transfer of a Recombinant Human \$\alpha_1\$-Antitrypsin cDNA to Human Endothelial Cells", <i>Proc. Natl. Acad. Sci. USA.</i> , 1992 , 89(14), 6482-6486			
EXAMINER		DATE CONSIDER	ED	

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OCT 0 2 2002

Sheet 8 of 15

Form Form	PTO-1449 Modified PTO-1449 Modified	2000 Decket No. SMAR-0013	Serial No. 10/019,341	
1	f Patent and Publications Cited by Applicant everal sheets if necessary)	Applicant Hayden, M.R. et al.		
	Department of Commerce at and Trademark Office	Filing Date May 3, 2002	Group Not Yet Assigned	
ОТНЕ	ER DOCUMENTS (Including Author	r, Title, Date, Pertine	nt Pages, Etc.)	
71	Liu, M-S. Et al., "Mapping of the epi monoclonal antibody (%D2) which in 1992, 1128(1), 113-115		_ •	
72	Liu, G. et al., "Efficient Adenovirus- Lipoprotein Lipase in Human Hepati 205-214	-	-	
73	Liu, G. et al., "Enhanced lipolysis in normal mice expressing liver-derived human lipoprotein lipase after", Clin. Invest. Med., 1998, 21(4-5), 172-185			
74	Liu, G. et al., "Phenotypic Correction of Feline Lipoprotein Lipase Deficiency by Adenoviral Gene Transfer", Hum. Gene. Ther., 2000, 11, 21-32			
75	Luckow, V.A. et al., "High Level Expression of Nonfused Foreign Genes with Autographa californica Nuclear Polyhedrosis Virus Expression Vectors", Virology 1989, 170, 31-39			
76	Lundman, P. MD. Et al., "Transient Triglyceridemia Decreases Vascular Reactivity i Young, Healthy Men Without Risk Factors for Coronary Heart Disease", <i>Circulation</i> 1997 , 96(10), 3266-3268			
77	Ma, Y. et al., "Two Naturally Occurr Codon Aspartic Acid 156 in the Prop Lipase", J. Biol. Chem., 1992, 267(3)	osed Catalytic Triad o		
. 78	Ma, Y. et al., "Mutagenesis in four candidate heparin binding regions (residues 279-282, 291-304, 390-393, and 439-448) and identification of residues affecting heparin binding of human lipoprotein lipase", J. Lipid. Res., 1994, 35(11), 2049-2059			
. 79	Ma, Y. et al., "A Missense Mutation (Asp250 Asn) in Exon 6 of the Human Lipoprotein Lipase Gene Causes Chylomicronemia in Patients of Different Ancestries", Genomics, 1992, 13, 649-653			
80	80 Ma, Y. et al., "A 4 basepair deletion in exon 4 of the human lipoprotein lipase gene results in type 1 hyperlipoproteinemia", <i>Human Molecular Genetics</i> , 1993, 2(7), 104 1050			
EXAMINER		DATE CONSIDER	ED	

OCT 0 2 2002

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Sheet 9 of 15

TRADEMARKS F	orm	PTO-1449 Modified	Docket No. SMAR-0013	Serial No. 10/019,341	
L	(Patent and Publications Cited by Applicant everal sheets if necessary)	Applicant Hayden, M.R. et al.		
		epartment of Commerce t and Trademark Office	Filing Date May 3, 2002	Group Not Yet Assigned	
. 0	THE	R DOCUMENTS (Including Author	r, Title, Date, Pertine	nt Pages, Etc.)	
	81	Ma, Y. et al., "Gene-Environment Int Phenotype in a Patient Homozygous Lipase Gene", J. Clin. Invest, 1993, 9	for a Ser 172 Cys Muta		
	82	Ma, Y. et al, "High frequency of mutations in the human lipoprotein lipase gene in pregnancy-induced chylomicronemia: possible association with apolipoprotein E2 isoform", J. Lipid. Res., 1994, 35(6), 1066-1075			
	83	Mailly, F. et al., "A Common Variant in the Gene for Lipoprotein Lipase (Asp9-Asn): Functional Implications and Prevalence in Normal and Hyperlipidemic Subjects", <i>Arterioscler. Thromb. Vasc. Biol.</i> , 1995, 15(4), 468-478			
	84	Marenberg, M.E. et al., "Genetic Susceptibility to Death from Coronary Heart Disease in a Study of Twins", New Engl. J. Med., 1994, 330, 1041-1046			
	85	Mattei, M.G. et al., "Assignment of the human lipoprotein lipase (LPL) gene to chromosome band 8p22", Cytogenet Cell Genet, 1993, 63, 45-46			
	Mattu, R.K. et al., "DNA Variants at the LPL Gene Locus Associate with Angiographically Defined Severity of Atherosclerosis and Serum Lipoprotein Levels in a Welsh Population", Arteriosclerosis and Thrombosis, 1994, 14, 1090-1097			Serum Lipoprotein Levels	
	87	McLaughlin, S.K. et al., "Adeno-Asse Analysis of Proviral Structures", J. V			
	88	Miller, A.D. "Progress Toward Huma	an Gene Therapy", Blo	od, 1990 , 76(2), 271-278	
	89	Monsalve, M.V. et al, "A Missense Mutation at Codon 188 of the Human Lipoprotein Lipase Gene Is a Frequent Cause of Lipoprotein Lipase Deficiency in Persons of Different Ancestries", J. Clin. Invest, 1990, 86(3), 728-734			
	Moss, J. "Peptide Prodrugs Designed to Limit Metabolism, Rationale and Applications of the Prodrug Concept for Pwptides", Peptide-Based Drug Design: Controlling Transport and Metabolism, 1995, 18, 423-448				
EXAMINER			DATE CONSIDERI	ED	
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OCT 0 2 2002

TECH CENTER 1600/2900

Sheet 10 of 15

TRADEMARY	Form 1	PTO-1449 Modified	Docket No. SMAR-0013	Serial No. 10/019,341	
	List of Patent and Publications Cited by Applicant (Use several sheets if necessary)				
		epartment of Commerce and Trademark Office	Filing Date May 3, 2002	Group Not Yet Assigned	
•	OTHE	R DOCUMENTS (Including Author	r, Title, Date, Pertine	nt Pages, Etc.)	
	91	Murthy, V. et al., "Molecular Pathol Pharmacol. Ther., 1996, 70(2), 101-		Lipoprotein Lipase Gene",	
	92	92 Muzyczka, N., "Use of Adeno-Associated Virus as a General Transduction Vector for Mammalian Cells", Curr. Topics in Micro. And Immunol., 1992, 158, 97-129			
	93	Needleman, S.B. et al., "A General Method Applicable to the Search for Similar in the Amino Acid Sequence of Two Proteins", . Mol. Biol., 1970, 48, 443-453			
	94	Nilsson-Ehle, P. et al., "A stable, rad lipoprotein lipase", J. Lipid. Res., 19	radioactive substrate emulsion for assay of 1976, 17, 536-541		
	95	Olivecrona, G. et al., "Transport of l Artherosclerosis X. Woodford et al,	of lipoprotein lipase and lipoprotein metabolism", al, eds., 250-253		
	96	Olivecrona, G. et al., "Noncatalytic Enzymol, 1997, 286, 102-116	functions of Lipoprote	in Lipase", Methods	
	97	Pearson, W.R. et al., "Improved Too Natl. Acad. Sci. USA., 1988, 85(8), 2		ence Comparasion", Proc.	
	Pimstone, S.N. et al., "A frequently occurring mutation in the lipoprotein lipase ger (Asn291Ser) results in altered postprandial chylomicron triglyceride andretinyl palmitate response in normolipidemic carriers", J. Lipid. Res., 1996, 37, 1675-1684			iglyceride andretinyl	
	99	Quantin, B. et al., "Adenovirus as an Expression Vecotr in Muscle Cells in vivo", Proc. Natl. Acad. Sci. USA, 1992, 89(7), 2581-2584			
	100	Quyyumi, A.A. et al., "Nitric Oxide Activity in the Human Coronary Circulation", J. Clin. Invest., 1995, 95, 1747-1755			
EXAMINER DATE CONSIDERED				ED	

OCT 0 2 2002

Service Mr.		TECH CENTER 1600/2900		Sheet 11 of 15	
TRAUE TRAUE	Form	PTO-1449 Modified	Docket No. SMAR-0013	Serial No. 10/019,341	
	List of Patent and Publications Cited by Applicant (Use several sheets if necessary)				
		Department of Commerce and Trademark Office	Filing Date May 3, 2002	Group Not Yet Assigned	
	OTHE	R DOCUMENTS (Including Author	r, Title, Date, Pertine	nt Pages, Etc.)	
	101	Reichardt, J.K. V. et al., "Genetic Va Implications for Prostate Cancer Risk	-		
	102		n Lipase Synergizes with Interferon Gamma to Induce on the tase mRNA Expression and Nitric Oxide romb. Vasc. Biol., 1995, 15, 392-399		
	103	Reymer, P. W.A. et al., "A lipoprotein lipase mutation (Asn291Ser) is associated with reduced HDL cholesterol levels in premature atherosclerosis", <i>Nat. Genet.</i> , 1995 , 10, 28-33			
	104	Rosenfeld, M.A. et al., "Adenovirus-Antitrypsin Gene to the Lung Epithel		- 1	
	105	Rosenfeld, M.A. et al., "In Vivo Transfer of the Human Cystic Fibrosis Transmembrane Conductance Regulator Gene to the Airway Epithelium", Cell, 1992 68, 143-155			
	106	Samson, M. et al., "Resistance to HIV mutant alleles of the CCR-5 chemoki		<u> </u>	
	107	Samulski, R.J. et al, "Helper-Free Stocks of Recombinant Adeno-Associated Viruses: Normal Integration Does Not Require Viral Gene Expression", J. Virol, 1989, 63,(9), 3822-3828			
*	108	SAS Institute, Inc., SAS/STAT Software: Changes and Enhancements through release 6.11. Cary, NC: SAS Institute, Inc.			
	109	Schultz, L.D. et al., "Expression and glycoprotein derived from Epstein-Ba	<u>•</u>	-	
•	110	Seed, B. "An LFA-3 cDNA encodes homologous to its receptor CD2", Na		-	

DATE CONSIDERED

EXAMINER

OCT 0 2 2002

Sheet 12 of 15

Form Form	PTO-1449 MEGHCENTER 1600/29	OPocket No. SMAR-0013	Serial No. 10/019,341			
List of Patent and Publications Cited by Applicant (Use several sheets if necessary)		Applicant Hayden, M.R. et al.				
U.S. Department of Commerce Patent and Trademark Office		Filing Date May 3, 2002	Group Not Yet Assigned			
ОТНЕ	R DOCUMENTS (Including Author	r, Title, Date, Pertine	nt Pages, Etc.)			
111	Sing, K. et al., "Lipoprotein lipase ge progression/regression of coronary at clinical events Lipoprotein and Coron 1999, 144, 435-442	herosclerosis, response	e to therapy, and future			
112	Smith, T.F. et al., "Comparasion of Biosequences", Adv. Appl. Math., 1981, 2, 482-489					
113	Smith, G.E. et al., "Production of Human Beta Interferon in Insect Cells Infected with a Baculovirus Expression Vecotr", <i>Mol. Cell. Biol.</i> , 1983 , 3(12), 2156-2165					
114	Sparkes, R.S. et al., "Human Genes Involved in Lipolysis of Plasma Lipoproteins: Mpping of Loci for Lipoprotein Lipase to 8p22 and Hepatic Lipase to 15q21", Genomics, 1987, 1(2), 138-144					
115	Steinberg, H.O. MD., "Endothelial Dysfunction is Associated with Cholesterol Levels in the High Normal Range in Humans", <i>Circulation</i> , 1997 , 96(10), 3287-3293					
116	Stocks, J. et al., "Lipoprotein lipase genotypes for a common premature termination codon mutation detected by PCR-mediated site-directed mutagenesis and restriction digestion", J. Lipid. Res., 1992, 33, 853-857					
117	Strauss, J.G. et al., "Generation of ad 151, 158 (abstract)	Generation of adult LPL-deficeint mice", Atherosclerosis, 2000,				
118	Stroes, E. et al., "NO activity in familial combined hyperlipidemia: potential role of cholesterol remnants", <i>Cardiovasc. Res.</i> , 1997 , 36, 445-452					
. 119	Taskinen, M-R. Et al., "High density lipoprotein subfractions in relation to lipoprotein ipase activity of tissues in man-evidence for reciprocal regulation of HDL2 and HDL3 levels by lipoprotein lipase", <i>Clin. Chim. Act.</i> , 1981 , 112, 325-332					
120	Tratschin, J-D. et al., "Genetic Analysis of Adeno-Associated Virus: Properties of Deletion Mutants Constructed in Vitro and Evidence for an Adeno-Associated Virus Replication Function", J. Virol., 1984, 51(3), 611-619					
EXAMINER		DATE CONSIDER	ED			

OCT 0 2 2002

Sheet 13 of 15

Form PTO-1449 Modified 1600/2900 ocket No. Serial No. **SMAR-0013** 10/019,341 List of Patent and Publications Applicant Cited by Applicant Hayden, M.R. et al. (Use several sheets if necessary) U.S. Department of Commerce Filing Date Group May 3, 2002 Patent and Trademark Office Not Yet Assigned OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) Tratschin, J-D., et al., "Adeno-Associated Virus Vector for High Frequency 121 Integration, Expression, and Rescue of Genes in Mammalian Cells", Mol. Cell. Biol., **1985,** 5, 3251-3260 122 Tratschin, J-D. et al., "A Human Parovirus, Adeno-Associated Virus, as a Eucaryotic Vector: Transient xpression and Encapsidation of the Procaryotic Gene for Chloramphenicol Acetyltransferase", Mol. Cell. Biol., 1985, 4, 2072-2081 Van Beuschem, V.W. et al., "Long-Term Expression of Human Adenosine Deaminas 123 in Rhesus Monkeys Transplanted with Retrovirus-Infected Bone-Marrow Cells", Proc. Natl. Acad. Sci. USA, 1992, 89(16), 7640-7644 Vogel, R.A., MD. et al., "Effect of a Single High-Fat Meal on Endothelial Function in 124 Healthy Subjects", Am. J. Cardiol., 1997, 79, 350-354 Weinstock, P.H. et al., "Severe Hypertiglyceridemia, Reduced High Density 125 Lipoprotein, and Neonatal Death in Lipoprotein Lipase Knockout Mice", J. Clin. Invest., 1995, 96, 2555-2568 Wess, G. et al., "Modified Bile Acids:Preparation of 7α, 12α-Dihydroxy-3β- and 7α, 126 12α-Dihydroxy-3-α-(2-Hydroxyethoxy)-5β-Cholanic Acid and Their Biological Activity", Tetrahedron Letters, 1992, 33, 195-198 Wess, G. et al., "Preparation of 3α-and 3β-(w-Aminoalkoxy)-7α, 12α-Dihydroxy-5β-127 Cholanoic Acid Esters: Versatile Shuttles for Drug Targeting", Tetrahedron Letters, **1992,** 34(5), 817-822 Wilcox, J.N. et al., "Expression of Multiple Isoforms of Nitric Oxide Synthase in 128 Normal and Atherosclerotic Vessels", Arterioscler. Thromb. Vasc. Biol., 1997, 17(11), 2479-2488 Wilson, et al., "Prevalence of Coronary Heart Disease in the Framingham Offspirng 129 Study: Role of Lipoprotein Cholesterols", Am. J. Cardiol., 1980, 46, 649-654 Wilson, J.M. et al., "Retrovirus-Mediated Transductions of Adult Hepatocytes", Proc. 130 Natl. Acad. Sci. USA., 1988, 85(9), 3014-3018 **EXAMINER DATE CONSIDERED**

OCT 0 2 2002

TECH CENTER 1600/2900

Sheet 14 of 15

	7	TEOH OLIVIER 10	00/2900	Sheet 14 of 15		
PRADEMARK	Form	PTO-1449 Modified	Docket No. SMAR-0013	Serial No. 10/019,341		
	List of Patent and Publications Cited by Applicant (Use several sheets if necessary)		Applicant Hayden, M.R. et al.			
		Department of Commerce t and Trademark Office	Filing Date May 3, 2002	Group Not Yet Assigned		
	ОТНЕ	R DOCUMENTS (Including Author	r, Title, Date, Pertine	nt Pages, Etc.)		
	131	Wilson, J.M. et al., "Hepatocyte-direct Improvement of Hypercholesterolem deficient Rabbits", J. Biol. Chem., 19	ia in Low Density Lipo			
	132	Science, 1987, 235(4796), 1638-1641				
	133					
	134	Wittrup, H.H. MD, PhD. et al., "Lipoprotein Lipase Mutations, Plasma Lipids and Lipoproteins, and Risk of Ischemic Heart Disease: A Meta-Analysis", Circulation, 1999, 99(22), 2901-2907				
	135	Wolff, J.A. et al., "Direct Gene Trans 247(4949), 1465-1468	fer into Mouse Muscle	e in Vivo", Science, 1990,		
	136	Wondisford, F.E. et al., "cloning of the Human Thyrotropin β-Subunit Gene and Transient Expression of Biologically Active Human Thyrotropin after Gene Transfection", <i>Mol. Endocrinol.</i> , 1988 , 2, 32-39				
	137	Wu, G.Y. et al., "Receptor-mediated <i>Chem.</i> , 1988 , 263(29), 14621-14624	G.Y. et al., "Receptor-mediated Gene Delivery and Expression in Vivo", J. Biol., 1988, 263(29), 14621-14624			
	138	Zechner, R. "The tissue-specific expression of lipoprotein lipase: implications for energy and lipoprotein metabolism", Curr. Opin. Lipidol., 1997, 8(2), 77-88				
•	139	Zhang, H. et al., "Patients with ApoE3 Deficiency (E2/2, E3/2, and E4/2) Who Manifest with Hyperlipidemia Have Increased Frequency of an Asn 291- Ser Mutation in the Human LPL Gene", <i>Arterioscler. Thromb. Vasc. Biol.</i> , 1995 , 15(10), 1695-1703				
	140	Zhang, H. et al., "Common sequence studies of in vitro expression and cata 1996, 1302, 159-166		-		
	141	Kastelein JJP., et al. "The Asn9 variant of lipoprotein lipase is associated with the- 93 G promoter mutation and an increased risk of coronary artery disease", <i>Clin Genet</i> , 1998, 53, 27-33				
EXAMINI	ER		DATE CONSIDER	ED		
<u> </u>						

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TECH CENTER 1600				00/4900 _{ket No.} SMAR-0013	Serial No. 10/019,3	D.	
	C	Patent and Publication Publication Patent and Publicant veral sheets if necessions.	Applicant Hayden, M.R. et al.				
U.S. Department of Commerce Patent and Trademark Office			Filing Date May 3, 2002	Group Not Yet Assigned			
· · · · · · · · · · · · · · · · · · ·		U.	S. PATENT D	OCUMENTS			
Examiner Initial		Document No.	Date	Name	Class	Subclass	
	142	4,554,101	11/19/85	Норр	260	112.5	
	143	4,868,116	09/19/89	Norgan, et al.	435	240.2	
	144	4,980,286	12/25/90	Morgan, et al.	435	172.3	
-	145	5,166,320	11/24/92	Wu, et al.	530	395	
	146	5,399,346	03/21/95	Anderson, et al.	424	93.21	
	147	5,658,729	08/19/97	Hayden, et al.	435	6	
		FORI	EIGN PATEN	T DOCUMENTS			
Examiner Initial		Document No.	Date	Country	YES To	Translation YES NO	
	148	WO 89/07136	08/10/89	PCT			
	149	WO 89/02468	03/23/89	PCT			
	150	WO 89/05345	06/15/89	PCT			
	151	WO 92/07573	05/14/92	PCT			
•	152	WO 95/05452	02/23/95	PCT			
	153	WO 95/27512	10/19/95	PCt .			

EXAMINER

DATE CONSIDERED